

1 Title: An Apparatus and Method of Use of a Circular Surgical Stapler

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4 **BACKGROUND OF THE INVENTION**

5 This invention relates to an improved surgical stapling instrument and method for  
6 joining hollow body organs, including but not limited to the bowels, rectum and intestines.  
7 More particularly, the present invention relates to the use of an evacuating stapling head  
8 assembly in cooperation with an anvil assembly to draw a portion of the hollow body organ  
9 into the head for transecting the drawn portion and stapling the ends of the remaining organ  
10 section to close the transaction site.

11 Circular surgical stapling devices are well known in the art. U.S. Patent  
12 Nos. 5,522,543 and 6,083,241 are typical of this prior art. Particularly informative of the  
13 state of the art is U.S. Patent No. 6,102,271 to Lango, et al., which patent disclosure is  
14 incorporated herein for all purposes.

15 Stapled rectal mucosectomy or anopexy consist in the relocation of prolapsing  
16 hemorrhoids to their anatomical place within the anal canal by means of a circumferential  
17 resection of the redundant mucosa situated above the hemorrhoids.

18 The most difficult step in the procedure for mucosa prolapse and hemorrhoids is  
19 placement of the purse-string suture. U.S. Patent No. 6,102,271 discloses the step of the  
20 procedure in sufficient detail for comprehension by one of ordinary skill in the art. Briefly,

1 the purse string is placed using the purse string anoscope in a circumferential manner at 4 cm  
2 proximal to the dentate line. Placing the purse string at the correct position can be difficult  
3 due to poor lighting and visualization of the anal canal through the purse string device.  
4 There has been an association between incorporating longitudinal muscle fibers of the  
5 rectum and fibers of the internal anal sphincter in the resected doughnut. The development  
6 of severe anal pain, fecal urgency and even some cases of perforation with local sepsis can  
7 be associated to purse string misplacement. It is believed that the technical issues regarding  
8 these complications have to do with the misplacement of the purse-string suture. The present  
9 invention method and apparatus completely eliminates the need for this risky purse-string  
10 suturing step in a hemorrhoidectomy.

11 SUMMARY OF THE INVENTION

12 The present invention includes a circular stapler having a sealed housing or casing  
13 and a mechanism for developing a negative pressure or suction within the housing. Suction  
14 is applied to draw the prolapsed mucous membrane into the stapling device. An appropriate  
15 level of section is dependent upon the structural strength of the patient's membrane. Normal  
16 evacuating pressures are in the range of about 80 psi to about 300 psi. Only sufficient  
17 suction pressure to incorporate the mucous membrane is applied leaving out the rectal wall.

18 The present invention method involves the introduction of a circular anal cannula.  
19 This reduces the prolapse and parts of the anal mucous membrane. The cannula is then fixed  
20 to the anal verge with four stitches at the flange edges of the cannula.

1           The casing of the inventive circular stapler is then introduced to approximately 2 cm  
2 proximal to the dentate line and is opened to its maximum position. Then an effective  
3 amount of suction is applied so that there is a complete draw of all the mucous prolapse and  
4 hemorrhoid tissue into the casing of the circular stapler. The stapler is then closed or  
5 tightened and fired. It is closed for 20 seconds after firing to help promote hemostasis. The  
6 instrument is slightly open for extraction. The staple line is checked for bleeding and  
7 additional sutures may be placed, as necessary.

8                           **BRIEF DESCRIPTION OF THE DRAWINGS**

9           Fig. 1 illustrates a prospective view of the stapler of the present invention in the open  
10 position.

11           Fig. 2 is a cross-section, side elevational view of the stapler of the present invention  
12 shown in the open position.

13           Fig. 3 is a cross-sectional view of an anal introducer inserted into the anus of a  
14 patient wherein the anal cannula of the introducer is sutured into position and the surgical  
15 stapler in the open position has been inserted into the anus and suction initiated.

16           Fig. 4 is a cross-sectional view similar to Fig. 3, but the hemorrhoids have been  
17 drawn into the inner chamber of the stapler by the suction mechanism and the anvil assembly  
18 of the stapler head end has been closed upon the hemorrhoids prior to firing the stapler.

19           Fig. 5 is a cross-sectional view similar to Fig. 4, where the stapler has been fired to  
20 place staplers in the submucosul layer and to transect the hemorrhoidal tissue.

1           **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

2           U.S. Patent No. 6,102,271 (incorporated herein) provides an excellent disclosure of  
3   the basic construction of a prior art stapler prior to being modified into the present invention.  
4   A complete description of the underlying instrument may be fully understood therein, except  
5   for the incorporation of a suction mechanism to draw the hemorrhoid or other hollow body  
6   organ into the inner chamber of the modified stapler.

7           Fig. 1 illustrates a circular stapling instrument 10 having a head assembly 12, an  
8   outer housing 14 with an inner chamber 16 and an anvil assembly 18. The outer housing 14  
9   is adapted to receive and retain a first end vacuum tubing 20 with the section of the tubing  
10   attached to a vacuum pump (not shown) to draw a negative pressure inside the housing 14  
11   and within the inner chamber 16. One of ordinary skill in the art will know how to attach the  
12   tubing to such a vacuum pump to achieve a controllable negative pressure.

13          The head assembly 12 is capable of receiving a large amount of tissue as shown in  
14   Figs. 3-5. Guide marks 22 on the outer housing 14 enable the user to measure the depth of  
15   anal insertion of the instrument. The anvil assembly 18 is attached to a distal end of  
16   reciprocating drive shaft 19 at the anvil shaft 24.

17          The stapler 10 has a handle 26 and an anvil closure knob 28. Knob 28 enables the  
18   user to move the anvil assembly proximally or distally. A firing trigger 31 is movable from  
19   an open position to a closed position to form staples into the hollow body organ and to  
20   activate the blade 62 to transect the tissue to be removed.

1           A cross-sectional view of the present stapler 10 is shown in Fig. 2 with the vacuum  
2   tube 20 attached to the housing 14 and in communication with the inner chamber 16. Seals  
3   40 may be provided to confine the evacuation to the upper portion of the housing, but it  
4   should be understood that a negative pressure could be drawn through the entire stapler 10  
5   via the handle 26 and housing 14 if an alternative vacuum tube 20' (Fig. 1 broken lines) is  
6   installed at the handle end of the stapler 10.

7           Fig. 2 shows a stapler driver 60 received in the housing 14, a annular cutting blade 62  
8   mounted within the distal end of the stapler driver 60, and a plurality of staples 64. As the  
9   stapler 10 is fired, the driver 60 moves from a first position (shown in Figs. 2, 3 and 4) to a  
10   second position (Fig. 5) whereby the cutting blade 62 transects the organ and the staples 64  
11   close the cut.

12          Fig. 3-5 illustrates the method of the present invention showing the stapler 10  
13   inserted into the anus 70 and rectum 72 of the patient. The stapler head assembly 12 is  
14   positioned such that the internal hemorrhoids 74 are located between the anvil 18 and the top  
15   edge 13 of the head housing 14 with the anvil 18 in the open position. Fig. 3 shows the anvil  
16   slightly retracted beginning to "pinch" the hemorrhoid 74. As should be understood by one  
17   of ordinary skill in the art, the stapler 10 has been inserted through an anal cannula 76  
18   sutured to the anus 70 by a series of retaining sutures 78.

19          Fig. 4 shows that a vacuum or negative pressure has been drawn through the vacuum  
20   tubes 20 and the hemorrhoid 74 drawn into the inner chamber 16 of the housing 14 and the

1 anvil 18 has been further tightened or retracted to bring it closer to the edge 13 of the  
2 housing 14. The amount of suction required to draw the hemorrhoid into the chamber is just  
3 sufficient to pull the mucosal tissue but not the rectal wall 80. Dependent upon the structural  
4 strength of the hemorrhoid and the rectal wall, the effective negative pressure may be in the  
5 approximate range of 80 psi to approximately 300 psi.

6 Fig. 5 illustrates the complete closure of anvil 18 upon the housing 14 pinching the  
7 tissue and the stapler 10 having been fired to drive the cutting blade 62 and to insert staples  
8 so as to transect and staple the hollow body organ. The evacuating mechanism continues to  
9 draw the removed or transected tissue into the inner chamber. The evacuation is shut off  
10 when the stapler has been fired.

11 The stapler should be maintained in the closed position for at least twenty seconds to  
12 promote hemostasis. The anvil is opened slightly for extraction of the instrument with the  
13 removed tissue retained in the inner chamber. Further procedures to ensure successful  
14 transection of the hollow body organ are then followed by the surgeon to complete the  
15 hemorrhoidectomy.

16 Although the invention has been described with reference to specific embodiments,  
17 this description is not meant to be construed in a limited sense. Various modifications of the  
18 disclosed embodiments, as well as alternative embodiments of the inventions will become  
19 apparent to persons skilled in the art upon the reference to the description of the invention. It

1 is, therefore, contemplated that the appended claims will cover such modifications that fall  
2 within the scope of the invention.